

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
23-R-0012

CUSTOMER NO.
286

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

GLAXO SMITH KLINE
709 SWEDELAND ROAD, P.O. BOX 1539
KING OF PRUSSIA, PA 19406
(610) 270-4800

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3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS/sites

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	89	565	487	10	1062
5. Cats	9	0	110	0	110
6. Guinea Pigs	53	276	1236	0	1512
7. Hamsters	0	164	62	0	226
8. Rabbits	115	47	1632	12	1691
9. Non-Human Primates	146	236	647	13	896
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Ferrets	15	0	0	1	1

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

(Certify that the above is true, correct, and complete (7 U.S.C. Section 2143))

b6; b7c/c

DATE SIGNED
11/15/07

PART 1 - HEADQUARTERS

(AUG 91)

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Explanation of Animals Listed in Column E
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Ferrets

One (1) ferret is listed in Column E.

Studies for development of novel anti-emetic compounds for the treatment of chemotherapy induced emesis

One (1) ferret was involved in a study to evaluate novel anti-emetic compounds. The animal was given a combination of known anti-emetic compounds then given a known agent that causes vomiting and closely monitored. The animal exhibited intermittent emesis during a 6 hour period. The animal was euthanized shortly after the end of the 6 hour study. Known anti-emetic compounds or analgesics were not given because of interference with study results.

Dogs

Ten (10) dogs are listed in Column E.

Osteoarthritis Study

Eight (8) dogs were assigned to an osteoarthritis study. Dogs on study underwent intra-articular sampling and injection while under anesthesia. Some of the dogs exhibited lameness after the procedure but usually for only a few hours. No pain relieving drugs could be given because the drugs affect cytokine production and/or inflammation that would interfere with interpretation of data.

GLP Dose Range Study

Two (2) dogs were part of a Safety Assessment study that was conducted in accordance with US Food and Drug Administration Good Laboratory Practice for Non-clinical Laboratory Studies, 21 CFR Part 58. The dogs were used in a dose range finding study. They experienced unanticipated neurological signs (semi-comatose state, seizure-like behavior). The signs then subsided. The dogs were dosed the next week with the same drug at a lower dose and they again experienced neurological signs. The dogs were then euthanized. Treating the dogs with anesthetics or analgesics would have interfered with the documentation of the disease process for drug safety assessment.

Nonhuman Primates

Thirteen (13) monkeys are listed in Column E.

Studies evaluating thyroid hormone metabolism and pharmacokinetics

Thirteen (13) monkeys were used on a study to evaluate thyroid hormone metabolism and pharmacokinetics of novel compounds used to treat thyroid hormone abnormalities. Animals were required to fast beyond 24 hours based on published findings that a greater than 24-hour fast was necessary to get the required baseline levels of thyroid hormone for the study. No animals were observed with abnormal clinical signs.

Rabbits

Twelve (12) rabbits are listed in Column E.

Osteoarthritis study

Twelve (12) rabbits were assigned to an osteoarthritis study. Rabbits on study underwent intra-articular sampling and injection while under anesthesia. No lameness was noted in the rabbits at any time during the study. No pain relieving drugs could be given because the drugs affect cytokine production and/or inflammation that would interfere with interpretation of data.